

#### REMARKS

This paper is a Response to the Final Office Action mailed November 10, 2008. Claims 40, 42 to 47 and 53 to 76 are pending. Claims 40, 42 to 47 and 53 to 76 are under consideration.

Applicants respectfully request entry of the Response since the amendment to claim 40 does not raise any new issues in that the amendment simply emphasizes that the two layers are distinct from each other. The amendment to claim 53 was made in order to delete reference to trademark designations and also does not raise any new issues. Furthermore, the amendments place the claims in better condition for allowance or Appeal. Accordingly, entry and consideration of the Response on the merits is respectfully requested.

#### Regarding the Amendments to the Specification

The amendments to the specification were made to address an informality. In particular, the specification has been amended to capitalize trademark designations. Thus, as the amendments were made to address an informality, no new matter has been added and entry thereof is respectfully requested.

#### Regarding the Claim Amendments

The claim amendments are supported throughout the specification or were made to address an informality. In particular, the amendment to claim 40 to recite, "wherein said second layer is substantially free of PVP when said first layer comprises PVP, and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP" is supported, for example, by originally filed claims 5 and 6 (see, also, page 9, second paragraph; page 10, second and third paragraphs; Example 1.1, page 39 to 40; and Example 5.1 page 45). The amendment to claim 44 to delete reference to PVP and PVPP was made in view of the amendment to claim 40, and to correct a grammatical error. The amendment to claim 53 to replace trademarks and recite, "agarose, dextran, an acrylamide based resin, or acrylamide," is supported, for example, at page 13, paragraph 3. Thus, as the claim amendments are supported throughout the specification or were made to address an informality, no new matter has been added and entry thereof is respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. §102(b)

The rejection of claims 40, 42 to 47 and 53 to 59 under 35 U.S.C. §102(b) as allegedly anticipated by Young *et al.* (Appl Environ Microbiol 59:1972 (1993)), is respectfully traversed. The grounds for rejection are set forth at pages 5 and 6 of the Office Action.

Claims 40, 42 to 47 and 53 to 59 are not anticipated by Young *et al.* (Appl Environ Microbiol 59:1972 (1993)) under 35 U.S.C. §102(b). Nevertheless, solely in order to advance prosecution of the application, claims 40, 44 and 53 have been amended as set forth herein. The rejection will therefore be addressed with respect to the amended claims upon entry of this Response.

Claim 40, as amended, recites among other things a device comprising at least two layers which, among other things, has “a first layer that comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP), and a second layer, wherein the first layer is arranged above the second layer, *and wherein said second layer is substantially free of PVP when said first layer comprises PVP, and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP.*” Accordingly, the two layers of the claimed device are distinct from each other. In contrast, at most Young *et al.* describe “the addition of PVP to a standard agarose gel” which is a single layer (see, e.g., abstract; page 1972, left column; and page 1973, left column) and not a device comprising at least two layers. Furthermore, Young *et al.* fail to suggest a device comprising a first and second layer, wherein the first layer comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP), and the first layer is arranged above the second layer, and wherein said second layer is substantially free of PVP when said first layer comprises PVP, and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP. Thus, Young *et al.* fail to teach or suggest each and every element of claims 40, 42 to 47 and 53 to 59. Consequently, claims 40, 42 to 47 and 53 to 59 are not anticipated by Young *et al.* and the rejection under 35 U.S.C. §102(b) must be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §112

The rejection of claim 43 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement is respectfully traversed. The grounds for rejection are set forth at pages 7 and 8 of the Office Action. In particular, the amendment to

claim 43 to recite the various components filed in the August 6, 2008 Response allegedly lacks adequate support.

Support for the amendment to claim 43 in the Response filed August 6, 2008 can be found throughout the specification. In particular, for example, the specification discloses at page 9, paragraph 3, that "Further examples of corresponding components of said first layer (i.e. inactivators of ....are functional molecules like CTAB, EDTA, EGTA, cyclodextrins,.... (see, also, page 12, paragraphs 4 and 5). Thus, in view of the specification it is clear that the recited inhibitors can be in the first layer in addition to the constituents of PVP or PVPP. Consequently, as claim 43 is adequately supported by the as-filed specification, the rejection under 35 U.S.C. §112, first paragraph, must be withdrawn.

The rejection of claim 53 under 35 U.S.C. §112, second paragraph, as allegedly indefinite is respectfully traversed. Allegedly the use of the trademark designations renders claim 53 indefinite.

Claim 53 is clear and definite as written. Nevertheless, solely in order to advance prosecution of the application, claim 53 has been amended as set forth herein. In particular, amended claim 53 does not recite trademarks. As such, the grounds for rejection of claim 53 under 35 U.S.C. §112, second paragraph is moot.

### III. REJECTIONS UNDER 35 U.S.C. §103

The rejection of claims 40, 42 to 46 and 53 to 59 under 35 U.S.C. §103(a), as allegedly unpatentable over Coffman (WO 99/00168) in view of Berthelet *et al.* (FEMS Microbiol. Lett. 138:17 (1996)) is respectfully traversed. Allegedly claims 40, 42 to 46 and 53 to 59 would have been obvious in view of the cited publications at the time of the invention.

Claims 40, 42 to 46 and 53 to 59 would not have been obvious under 35 U.S.C. §103(a) in view of Coffman (WO 99/00168) and Berthelet *et al.* (FEMS Microbiol. Lett. 138:17 (1996)) at the time of the invention. Nevertheless, solely in order to advance prosecution of the application, the claims have been amended as set forth herein. The rejection will therefore be addressed with respect to the amended claims upon entry of this Response.

In order for a rejection to be proper under 35 U.S.C. §103(a), there must have been at the time of the invention: 1) a suggestion or motivation to modify or combine the references at

the time of the invention; 2) a reasonable expectation of success of producing the claimed invention; and 3) the combined references must teach or suggest each and every claim limitation. Both the teaching or suggestion to make the claimed combination and reasonable expectation of success must both be found in the prior art, not in Applicants' disclosure. See, e.g., *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991) and *In re O'Farrell*, 853 F.2d 894, 903-904 (Fed. Cir. 1988). [R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); see also, *KSR International Co., v. Teleflex Inc.*, 82 U.S.P.Q. 1385, 1396 (U.S. 2007)- "a patent composed of several elements is not proved obvious by merely demonstrating that each of its elements was, independently, known in the prior art. Furthermore, the prior art must be considered in its entirety....including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).

Here, *inter alia*, the cited references fail to teach or suggest teach and every limitation of claims 40, 42 to 46 and 53 to 59. As discussed above, amended claim 40 requires that the device have two distinct layers, namely a first layer being adapted to bind or inactivate inhibitors of the activity of reagents or enzymes used in nucleic acid manipulation, wherein said first layer comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP), and a second layer being adapted to separate a plurality of nucleic acid molecules with respect to their size, and wherein said first layer is a first phase of a gel and said second layer is a second phase of said gel, wherein said first layer is arranged above the second layer, and wherein said second layer is substantially free of PVP when said first layer comprises PVP, and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP. Thus, the first layer comprises either polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP), and when the first layer comprises PVP the second layer is substantially free of PVP, and when the first layer comprises PVPP, the second layer is substantially free of PVPP.

In contrast neither Coffman nor Berthelet *et al.* alone or in combination describe a device with two layers in which the first layer is adapted to bind or inactivate inhibitors of the activity of reagents or enzymes used in nucleic acid manipulation, wherein said first layer comprises polyvinylpyrrolidone (PVP) or polyvinylpolypyrrolidone (PVPP), and the second layer is adapted to separate a plurality of nucleic acid molecules with respect to their size, and

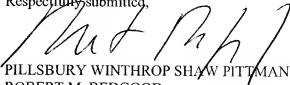
wherein said first layer is a first phase of a gel and said second layer is a second phase of said gel, wherein said first layer is arranged above the second layer, and wherein said second layer is substantially free of PVP when said first layer comprises PVP, and wherein said second layer is substantially free of PVPP when said first layer comprises PVPP. In this regard, there is no teaching or suggestion in either Coffman or Berthelet *et al.* alone, or in combination, to produce a claimed device wherein, among other things, when the first layer comprises PVP, then the second layer is substantially free of PVP, and when the first layer comprises PVPP, then the second layer is substantially free of PVPP.

In view of the fact that neither Coffman (WO 99/00168) nor Berthelet *et al.* (FEMS Microbiol. Lett. 138:17 (1996)) alone, or in combination, teach or suggest each and every element of claims 40, 42 to 46 and 53 to 59, the claims would not have been obvious under 35 U.S.C. §103(a) at the time of the invention. Consequently, the rejection under 35 U.S.C. §103(a) is improper and must be withdrawn.

In summary, for the reasons set forth herein, Applicants maintain that claims 40, 42 to 47 and 53 to 76 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims that are now under consideration.

Please charge any fees associated with the submission of this paper to Deposit Account Number 033975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,



PILLSBURY WINTHROP SHAW PITTMAN LLP  
ROBERT M. BEDGOOD  
Reg. No. 43488  
Tel. No. 858.509.4065  
Fax No.

Date: January 12, 2009  
12255 El Camino Real  
Suite 300  
San Diego, CA 92130-4088  
(619) 234-5000